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Attorney Docket No.: 6248.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Andersen et al.

Serial No.: 10/068,224 Group Art Unit: 3728

Filed: February 5, 2002 Examiner: Jimmy G. Foster

For: Composition for IVF

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Express Mail Label No. EV 409530987 US

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I hereby certify that the attached correspondence comprising:

1. Petition under 37 C.F.R. § 1.181
2. Declaration of Tracy Bronner
3. Copy of Request for Customer Number Data Change (Exhbit A of Declaration)
4. Copy of Notice of Customer Number Record Change (Exhibit B)
5. Copy of Palm Spreadsheet (Exhibit C)
6. Copy of Express Mail Label and Signature Page referencing Amendment (Exhibit D)
7. Change of Address Letter
8. Copy of Certificate of Facsimile Transmission
9. Copy of Petition and Fee for Extension of Time
10. Copy of Amendment Fee Transmittal
11. Copy of Response to Office Action

is being deposited with the United States Postal Service as Express Mail in an envelope addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

On August 4, 2004

Csaba Attila Szakolczai
(name of person mailing paper)

Csaba Attila Szakolczai
(signature of person mailing paper)

08-05-04 IFW DAC

Use the following customer number for all correspondence regarding this application:

23650

PATENT TRADEMARK OFFICE

Attorney Docket No.: 6248.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Andersen

Application No.: 10/068,224 Group Art Unit: 3728

Filed: February 5, 2002 Examiner: FOSTER, J.

For: COMPOSITIONS FOR IVF

PETITION UNDER 37 C.F.R. § 1.181

Director, US Patent and Trademark Office
Mail Stop Petitions
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants hereby request that the period for responding to the Office Action of February 18, 2004 in the above-referenced patent application be re-set and any extension fees paid in connection with the most recent Amendment filed in response to this Office Action be refunded, as the Office Action was improperly mailed and never received by Applicants' representatives.

Applicants' representatives changed addresses in 2002. Prior to the mailing of the February 18, 2004 Office Action, Applicants' representatives provided their new address in association with their customer number, 23650, and identified this case as associated therewith both in a spreadsheet of associated applications in the most recent substantive paper (an Amendment filed in November 2003). Nonetheless, the Office Action was mailed to Applicants' representatives' old address and apparently thereafter returned by the US Postal Service to the Office with no further action taken concerning the matter on the part of the

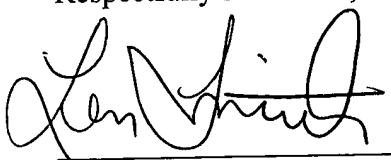
Office. Applicants' representatives only recently discovered this matter during a review of PAIR and have promptly taken action to resolve the matter. In all similar cases that have arisen, the Office has re-set the time for response. These facts are established by the Declaration of Tracy Bronner, Docketing Coordinator for the NNPI Patent Department, which is submitted herewith.

In view of these facts, Applicants respectfully request that the period for responding to the Office Action of February 18, 2004 be re-set and that the extension of time fees paid in connection with the Response to Office Action filed in response thereto (filed with the Office separately but concurrently) be refunded to Applicants' by depositing such refund to Deposit Account No. 14-1447. Such action is in accordance with the spirit of MPEP § 710.06.

Applicants note that a procedure for re-setting the period for response in similar situations is set forth in 1160 OG 14 (1994), wherein the Tech Center Director is authorized to review such petitions. Inasmuch as the facts here do not fit within the specific matters governed by 1160 OG 14 (e.g., the Office Action has never been "received" by Applicants), Applicants have submitted this Petition under Rule 181. If this procedure is in any way in error, Applicants request that this Petition be submitted to the Tech Center Director for review of this matter as a petition thereto.

Please charge the required fee, estimated to be $130.00, to Novo Nordisk of North America, Inc., Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

Respectfully submitted,



Date: August 4, 2004

Len S. Smith, Reg. No. 43,139
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5800

Use the following customer number for all correspondence regarding this application.

23650

23650

PATENT TRADEMARK OFFICE

Use the following customer number for all correspondence regarding this application.

23650

PATENT TRADEMARK OFFICE

Attorney Docket No.: 6248.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Andersen

Application No.: 10/068,224

Group Art Unit: 3728

Filed: February 5, 2002

Examiner: FOSTER, J.

For: COMPOSITIONS FOR IVF

DECLARATION OF TRACY BRONNER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, Tracy Bronner, hereby state:

1. I am the Docket Coordinator for the Patent Department of Novo Nordisk® Pharmaceuticals, Inc. ("NNPI"), the representatives of the applicants for the above-referenced patent application.

2. In 2002, the NNPI Patent Department relocated from its previous address at 405 Lexington Avenue, Suite 6400, New York, New York, 10174 to its current address at 100 College Road West, Princeton, New Jersey 08540. On September 11, 2002, a Request for Customer Number Data Change was filed with the Office providing this address for all applications associated with customer number 23650 (Exhibit A). A Notice of recordation of this change, dated September 12, 2002, was received in our office on September 26, 2002 (Exhibit B).

3. In accordance with my discussions with the US Patent and Trademark Office ("USPTO"), I submitted a spreadsheet of patent applications assigned to Novo Nordisk® for

association with this customer on November 12, 2003. Copies of the front page of this spreadsheet, page including a listing of this application, and express mail receipt for the mailing of this document to the USPTO are together attached hereto as Exhibit C.

4. Despite taking these and other steps, we have continued to encounter problems in not receiving correspondence from the USPTO including Office Actions. The USPTO instructed us to include a request to use our customer number on all substantive papers filed in connection with an application, such as was included in the previous Amendment, which was filed in November 2003 (a copy of the signature page thereof is attached hereto as Exhibit D). Nonetheless, mailing address issues have still persisted, resulting in Office Actions not reaching NNPI in a timely matter, if at all. In all such cases that we have become aware of to date, the USPTO has reset the period for response.

5. To deal with these problems, we have recently instituted a policy of periodically reviewing our internal docket records versus PAIR. It was through this process, on or about July 22, 2004, that we determined that the most recent Office Action in this case, dated February 18, 2004, was never sent to our current address even after being returned to the USPTO. It was on or about that date that I relayed this information to Len Smith of our Patent Department.

6. I hereby declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 8/2/04

Tracy Bronner, Docket Coordinator
Novo Nordisk Pharmaceuticals, Inc.

Please type a plus sign (+) inside this box →

PTO/SB/124A (08-00)
Approved for use through 10/31/2002. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Request for Customer Number Data Change

Address to:

Assistant Commissioner for Patents
Box CN
Washington, DC 20231

To the Commissioner of Patents and Trademarks:
Please record the following data changes to **Customer Number:**

Type Customer Number here: 141447 →

23650
PATENT TRADEMARK OFFICE

☒ Please change Correspondence Address to:

Firm *or* Individual Name	NOVO NORDISK PHARMACEUTICALS, INC.
Address	100 COLLEGE ROAD WEST
Address	
City	PRINCETON
State	NJ
ZIP	08540
Country	USA
Telephone	609-987-5931
Fax	609-919-7741

☒ Please **delete** the following practitioner registration number(s) from the Customer Number indicated above:

35,127
43,228
41,324

☒ Please **add** the following practitioner registration number(s) to the Customer Number indicated above:

45,220
48,829

☐ Additional practitioner registration numbers are listed on supplemental sheet(s) attached hereto

Request Submitted by:

Firm Name (if applicable)	NOVO NORDISK OF NORTH AMERICA, INC
Name of Person submitting request	REZA GREEN, Ph.D
Signature	by No 38,475
Telephone Number	609-987-5831
Date	9/11/02

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

CUSTOMER NUMBER: 23650

CORRESPONDENCE ADDRESS:

NOVO NORDISK OF NORTH AMERICA, INC
405 LEXINGTON AVENUE
SUITE 6400
NEW YORK, NY 10017

FAX: **PHONE:** 2128670123

E-MAIL:

Date Mailed: 09/12/2002

NOTICE OF CUSTOMER NUMBER RECORD CHANGE

The request to change the information associated with the above-identified Customer Number has been accepted by the Commissioner of Patents and Trademarks.

The Customer Number may be used to identify the correspondence address or "fee address" for, and/or the appointed practitioner(s) in, a United States patent application or patent. The correspondence address and registration numbers indicated on this notice reflect the current correpondence address and registration numbers associated with the above-identified Customer Number.

PRACTITIONER REGISTRATION NUMBER(S) ASSIGNED TO THAT CUSTOMER NUMBER:

30335, 33728, 34086, 36993, 38475, 45220, 48829.

[redacted]

Patents Electronic Business Center
(703) 305-3028

SEP 26 2002

PART 1 - ATTORNEY/APPLICANT COPY

	23650									
100 College Road West										
Princeton, NJ 08540										
							SN Associated?	SN not in PALM	PALM Patent Number	
4816439	00032053	03/28/89	03/27/87	Yes	no	Yes	No	SN NOT in PALM		38475
5106734	00043960	11/27/90	04/29/87	Yes	no	Yes	No	SN NOT in PALM		36459
4804669	00118399	06/29/93	11/09/87	Yes	no	Yes	No	SN NOT in PALM		48429
5140008	00262466	05/07/96	10/25/88	Yes	no	Yes	No	SN NOT in PALM		45220
325781	00345536	06/28/94	05/01/89	Yes	no	Yes	No	SN NOT in PALM		43139
5180583	00368967	01/19/93	06/19/89	Yes	no	Yes	No	SN NOT in PALM		
5180583	00368967	03/11/97	06/19/89	Yes	no	Yes	No	SN NOT in PALM		
5017493	00470396	10/21/97	01/25/90	Yes	no	Yes	No	SN NOT in PALM		
5045455	00538691	04/02/91	06/14/90	Yes	no	Yes	No	SN NOT in PALM		
5223124	00543770	03/07/95	02/03/89	Yes	no	Yes	No	SN NOT in PALM		
5202415	00623739	10/05/93	06/19/89	Yes	no	Yes	No	SN NOT in PALM		
4716117	00689274	04/23/91	01/07/85	Yes	no	Yes	No	SN NOT in PALM		
4916212	00739123	04/10/90	05/29/85	Yes	no	Yes	No	SN NOT in PALM		
5264444	00744725	03/21/00	08/14/91	Yes	no	Yes	No	SN NOT in PALM		
5190522	00745988	07/21/98	04/11/91	Yes	no	Yes	No	SN NOT in PALM		
5328925	00746104	02/20/96	08/15/91	Yes	no	Yes	No	SN NOT in PALM		
5403734	00776854	04/18/00	10/15/91	Yes	no	Yes	No	SN NOT in PALM		
4745122	00804810	04/08/97	12/04/85	Yes	no	Yes	No	SN NOT in PALM		
5250514	00807861	12/29/87	07/27/90	Yes	no	Yes	No	SN NOT in PALM		
4826763	00820144	01/19/93	01/21/86	Yes	no	Yes	No	SN NOT in PALM		
347894	00909944	02/08/94	07/07/92	Yes	no	Yes	No	SN NOT in PALM		
5324641	00952696	07/09/96	09/23/92	Yes	no	Yes	No	SN NOT in PALM		
4623619	06467843	04/10/90	02/18/83	Yes	no	Yes	No			
5004804	06570062	05/02/89	01/12/84	Yes	no	Yes	No			
4784950	06810002	01/19/93	12/16/85	Yes	no	Yes	No			
5618913	06901821	04/21/92	08/29/86	Yes	no	Yes	No			
5010090	07254557	12/13/94	10/07/88	Yes	no	Yes	No			
5037382	07301178	04/23/96	01/24/89	Yes	no	Yes	No			
4973318	07308399	06/04/96	02/09/89	Yes	no	Yes	No			
5043345	07401370	05/27/97	08/31/89	Yes	no	Yes	No			
5041455	07482272	05/21/91	02/20/90	Yes	no	Yes	No			
	07569376	09/03/91	08/13/90	Yes	no	Yes	No			
5373090	07598737	04/13/93	04/25/89	Yes	no	Yes	No			
5328923	07744150	11/25/97	08/13/91	Yes	no	Yes	No			
5260314	07744160	07/14/98	08/13/91	Yes	no	Yes	No			
5328924	07745033		08/14/91	Yes	no	Yes	No			
5284859	07745568	05/06/97	08/15/91	Yes	no	Yes	No			
5260311	07746378	12/15/98	08/16/91	Yes	no	Yes	No			
5149533	07747452	05/08/01	08/12/91	Yes	no	Yes	No			

	09969358		10/02/01	Yes	no	Yes	Yes			
	09972828		10/04/01	Yes	no	Yes	Yes			
6639515	09975814		10/11/01	Yes	no	Yes	Yes			
	09994971		10/19/99	Yes	no	Yes	Yes			
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	09996023		11/16/01	Yes	no	Yes	Yes			
	09996025		11/16/01	Yes	no	Yes	Yes			
	10002826		11/30/01	Yes	no	Yes	Yes			
	10007447	05/29/01	01/27/99	Yes	no	Yes	Yes			
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	10016858		12/14/01	Yes	no	Yes	Yes			
	10026032	07/04/00	09/04/98	Yes	no	Yes	Yes			
	10028540		12/19/01	Yes	no	Yes	Yes			
	10051044		07/14/00	Yes	no	Yes	Yes			
	10058436	08/21/01	05/23/95	Yes	no	Yes	Yes			
	10067895	12/04/01	12/18/96	Yes	no	Yes	Yes			
	10068224		02/05/02	Yes	no	Yes	Yes			
	10077260		02/14/02	Yes	no	Yes	Yes			
	10083058	02/20/01	10/23/98	Yes	no	Yes	Yes			
	10090011		02/26/02	Yes	no	Yes	Yes			
	10101454	07/29/97	02/02/94	Yes	no	Yes	Yes			
	10101456		03/12/02	Yes	no	Yes	Yes			
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	10114557		04/01/02	Yes	no	Yes	Yes			
	10132428		08/07/00	Yes	no	Yes	Yes			
	10140512		10/27/00	Yes	no	Yes	Yes			
	10141469		05/01/02	Yes	no	Yes	Yes			
	10151683		05/17/02	Yes	no	Yes	Yes			
	10166241		06/07/02	Yes	no	Yes	Yes			
	10166412		06/07/02	Yes	no	Yes	Yes			
	10172645		06/13/02	Yes	no	Yes	Yes			
	10172647		06/13/02	Yes	no	Yes	Yes			
	10176410		03/13/00	Yes	no	Yes	Yes			
	10179355		07/01/02	Yes	no	Yes	Yes			
	10185861		06/27/02	Yes	no	Yes	Yes			
	10185901		06/27/02	Yes	no	Yes	Yes			
	10185923		06/27/02	Yes	no	Yes	Yes			
	10186498		06/28/02	Yes	no	Yes	Yes			
	10187493		07/01/02	Yes	no	Yes	Yes			
	10191351		07/30/99	Yes	no	Yes	Yes			
	10191367		07/02/02	Yes	no	Yes	Yes			
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	10201456		07/19/02	Yes	no	Yes	Yes			
	10201865		03/16/01	Yes	no	Yes	Yes			
	10205270		07/24/02	Yes	no	Yes	Yes			
	10209567		04/17/00	Yes	no	Yes	Yes			
	10216680		08/07/02	Yes	no	Yes	Yes			
	10217594		07/29/02	Yes	no	Yes	Yes			
	10217595		07/29/02	Yes	no	Yes	Yes			
	10223739		08/23/02	Yes	no	Yes	Yes			

EV 246879728 US

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PO ZIP Code: 0836	Day of Delivery: ☒ Next ☐ Second	Flat Rate Envelope: ☐
Date In: Mo. 11 Day 12 Year 03	☒ 12 Noon ☐ 3 PM	Postage: $ 13.65
Time In: ☐ AM ☒ PM 0409	Military: ☐ 2nd Day ☐ 3rd Day	Return Receipt Fee
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Delivery Date: Mo. Day	Time: ☐ AM ☐ PM	Employee Signature

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FROM: (PLEASE PRINT) PHONE 609 987 5800
REZA GREEN
NOVO NORDISK PHARMACEUTICALS
100 COLLEGE RD W
PRINCETON NJ 08540-6604

TO: (PLEASE PRINT) PHONE ( )
MAIL STOP: EBC
COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA
22313-1450

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EMS

The application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

Date: November 24, 2003

Len S. Smith, Reg. No. 43,139
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5800

Use the following customer number for all correspondence regarding this application.

23650
PATENT TRADEMARK OFFICE

Attorney Docket No.: 6248.200-US PATENT

Use the following customer number for all correspondence regarding this application.

23650

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Andersen et al.

Serial No.: 10/068,224 Group Art Unit: 3728

Filed: February 5, 2002 Examiner: Jimmy G. Foster

For: Composition for IVF

REQUEST FOR CHANGE OF ADDRESS

Assistant Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Please address all correspondence in the instant case to:

Customer Number: 23560
i.e.
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540
Attention: Patent Department

Respectfully submitted,

Date: August 4, 2004

Reza Green, Reg. No. 38,475
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5800

Use the following customer number for all correspondence regarding this application.

23650
PATENT TRADEMARK OFFICE

Attorney Docket No.: 6248.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Andersen et al.

Serial No.: 10/068,224 Group Art Unit: 3728

Filed: February 5, 2002 Examiner: Jimmy G. Foster

For: Composition for IVF

PETITION AND FEE FOR EXTENSION OF TIME (37 C.F.R. 1.136(a))

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

It is respectfully requested that the time for response to the Office Action dated February 18, 2004 be extended for a period of 3 months from May 18, 2004 to August 18, 2004. Applicant hereby petitions for such extension of time.

Please charge the required fee, estimated to be $950.00 with this application and to credit any overpayments to Novo Nordisk Pharmaceuticals, Inc., Deposit Account No. 14-1447. Please charge any additional fees, should they be required, to Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

Respectfully submitted,

Date: August 3, 2004

Richard W. Bork, Reg. No. 36,459
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5800

Use the following customer number for all correspondence regarding this application.

23650
PATENT TRADEMARK OFFICE

Attorney Docket No.: 6248.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Andersen et al.

Serial No.: 10/068,224 Group Art Unit: 3728

Filed: February 5, 2002 Examiner: Jimmy G. Foster

For: Composition for IVF

AMENDMENT FEE TRANSMITTAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is an Amendment for the above-identified application in response to the Office Action mailed February 18, 2004.

The fee for claims has been calculated as shown below:

Total: 43 - 42 = 1 x18 = $18
Independent: 7 - 5 = 2 x86 = $172.

Total additional fee for claims required is $190.

In the event that an extension of time is required, Applicant hereby petitions for such extension of time. The Commissioner of Patents is authorized to charge the required fee, if applicable, to Deposit Account No. 14-1447.

Please charge the required claims fees, estimated to be $190., with this application and to credit any overpayments to Novo Nordisk of North America, Inc., Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

Respectfully submitted,

Date: August 3, 2004

Richard W. Bork, Reg. No. 36,459
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5800

Use the following customer number for all correspondence regarding this application.

23650
PATENT TRADEMARK OFFICE

Use the following customer number for all correspondence regarding this application.

23650

PATENT TRADEMARK OFFICE

Attorney Docket No.: 6248.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Andersen

Application No.: 10/068,224 Group Art Unit: 3728

Filed: February 5, 2002 Examiner: FOSTER, J.

For: COMPOSITIONS FOR IVF

RESPONSE TO OFFICE ACTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action dated February 18, 2004, please amend the above-captioned application and consider the provided remarks as follows:

Amendments to the Claims are reflected in the **Listing of Claims**, which begins on page 2 of this paper.

Remarks concerning the Office Action and the claim amendments begin on page 9 of this paper.

COPY

AMENDMENTS TO THE CLAIMS

~~The following Listing of Claims replaces all prior versions, and listings, of claims in this~~ Application.

LISTING OF CLAIMS

1. (previously presented) A composition comprising a meiosis activation substance in a container wherein the oxygen content in the container is less than about 0.01 moles oxygen per liter and the container is capable of maintaining the oxygen content.

2. (cancelled)

3. (previously presented) The composition of claim 1, wherein the oxygen content is less than about 0.001 moles of oxygen per liter.

4. (previously presented) The composition of claim 1, wherein the oxygen content is less than about 0.0001 moles of oxygen per liter.

5. (currently amended) A ~~composition~~ product comprising (A) a container capable of maintaining a low oxygen content and (B) a pharmaceutical composition contained therein that comprises ~~comprising~~ (i) a solid ~~composition of a~~ meiosis activation substance~~,~~ and (ii) an additive, ~~and (iii)~~ wherein the pharmaceutical composition is contained in an atmosphere with an oxygen content of less than 10% ~~contained therein, wherein the container is capable of maintaining the oxygen content~~.

6. (currently amended) The product ~~composition~~ of claim 5, wherein the solid composition of a meiosis activation substance has a high aqueous solubility.

7. (cancelled)

8. (currently amended) The ~~composition of~~ product of claim 5, wherein the oxygen content of the atmosphere is less than 5%.

9. (currently amended) The ~~composition of~~ product of claim 8, wherein the oxygen content of the atmosphere is less than 1%.

10. (currently amended) The ~~composition of~~ product of claim 5, wherein the atmosphere contains more than 90% nitrogen or argon.

11. (currently amended) The ~~composition of~~ product of claim 10 , wherein the ~~atmosphere contains more than 99% nitrogen or argon.~~

12. (currently amended) The ~~composition of~~ product of claim 5, wherein the solid meiosis activation substance ~~composition~~ has a water content of less than about 10%.

13. (currently amended) The ~~composition of~~ product of claim 12, wherein the solid meiosis activation substance ~~composition~~ has a water content of less than about 5%.

14. (currently amended) The ~~composition of~~ product of claim 13, wherein the solid meiosis activation substance ~~composition~~ has a water content of less than about 1%.

15. (currently amended) The ~~composition of~~ product of claim 5, wherein the solid meiosis activation substance ~~composition~~ has an organic solvent content of less than about 10%.

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16. (currently amended) The composition claim 15, wherein the solid meiosis activation substance ~~composition~~ has an organic solvent content of less than about 5%.

17. (currently amended) The ~~composition of~~ product of claim 16, wherein the solid meiosis activation substance ~~composition~~ has an organic solvent content of less than about 1%.

18. (currently amended) The ~~composition of~~ product of claim 5, wherein the meiosis activation substance content makes up less than about 10% of the pharmaceutical composition ~~contained in the container~~ by weight.

19. (currently amended) The ~~composition of~~ product of claim 18, wherein the meiosis activation substance makes up less than about 2% of the pharmaceutical composition ~~contained in the container~~ by weight.

20. (currently amended) The ~~composition of~~ product of claim 19, wherein the meiosis activation substance makes up less than about 1% of the pharmaceutical composition ~~contained in the container~~ by weight.

21. (previously presented) The composition of claim 1, wherein the meiosis activation substance is a compound exhibiting a percentage germinal vesicle breakdown which is 50% higher than a control.

22. (previously presented) The composition of claim 1, wherein the meiosis activation substance is 4,4-dimethyl-5α-cholesta-8,14,24-triene-3β-ol; 4,4-dimethyl-5α-cholest-8,14,24-trien-3β-ol hemisuccinate; 5α-cholest-8,14-dien-3β-ol; 5α-cholest-8,14-dien-3β-ol hemisuccinate; (20S)-cholest-5-en-3β,20-diol; 3β-hydroxy-4,4-dimethyl-5α-chola-8,14-dien-24-oic acid-N-(methionine) amide; cholest-5-en-16β-ol; or (20S)-20-[(piperidin-1-yl)methyl]-4,4-dimethyl-5α-pregna-8,14-dien-3β-ol.

23. (currently amended) The ~~composition of~~ product of claim 5, wherein the additive is a protein or a phosphoglyceride.

24. (currently amended) The ~~composition of~~ product of claim 23, wherein the additive is serum albumin.

25. (currently amended) The ~~composition of~~ product of claim 24, wherein the serum albumin is human serum albumin or recombinant human serum albumin.

26. (currently amended) The ~~composition of~~ product of claim 5, wherein the additive makes up at least about 90% of the content of the pharmaceutical composition ~~contained in the container~~.

27. (currently amended) The ~~composition of~~ product of ~~claim~~ 26, wherein the additive makes up at least about 98% of the pharmaceutical composition ~~contained in the container~~.

28. (currently amended) The ~~composition of~~ product of claim 27, wherein the additive makes up at least about 99% of the pharmaceutical composition ~~contained in the container.~~

29. (currently amended) The ~~composition of~~ product of claim 5, wherein the container comprises more than one ~~or more~~ hollow space ~~spaces~~ and at least one of the hollow spaces contains the pharmaceutical composition ~~a composition comprising (i) a solid composition a meiosis activation substance with a high aqueous solubility, (ii) the additive, and (iii) the atmosphere~~ .

30. (currently amended) A product comprising (A) a container and (B) a pharmaceutical composition contained therein that comprises ~~The composition of claim 5, wherein an aqueous media is added to the solid composition to form an aqueous solution~~ (i) a solid meiosis activation substance and (ii) an additive, wherein the pharmaceutical composition forms a solution comprising a dissolved form of the meiosis activation substance upon sufficient contact with an aqueous medium.

31. (currently amended) ~~The composition of~~ method of claim ~~30~~ 42, wherein the meiosis activation substance in the aqueous solution is in a concentration of at least about 100 μg/ml.

32. (currently amended) The ~~composition of~~ method of claim ~~30~~ 42, wherein the meiosis activation substance in the aqueous solution is in a concentration of at least about 10 μg/ml.

33. (currently amended) The ~~composition of~~ method of claim ~~30~~ 42, wherein the meiosis activation substance in the aqueous solution is in a concentration of at least about 1 μg/ml.

34. (currently amended) The ~~composition of~~ method of claim ~~30~~ 42, wherein the meiosis activation substance in the aqueous solution is in a concentration of at least about 0.001 μg/ml.

35. (currently amended) The ~~composition of~~ method of claim ~~30~~ 42, wherein the aqueous media has an organic solvent content of less than about 0.1%.

36. (currently amended) The ~~composition of~~ method of claim 35, wherein the aqueous media has an organic solvent content of less than about 0.05%.

37. (original) A process for preparing a pharmaceutical composition in a closed container, comprising:

a) preparing a solid composition comprising a meiosis activation substance and an additive;

b) adding the solid composition to the container;

c) freeze drying the composition; and

d) closing the container *in vacuo*.

38. (previously presented) The process of claim 37, wherein the preparation of the solid composition is performed *in vacuo*.

39. (previously presented) The process according to claim 37, wherein the preparation of the solid composition is performed in an atmosphere having an oxygen content of less than about 0.01 moles per liter.

40. (previously presented) A process for preparing a pharmaceutical composition in a closed container comprising:

a) preparing a solid composition comprising a meiosis activation substance and an additive;

b) filling the solid composition into the container;

c) filling the container with an atmosphere having an oxygen content of less than 10%; and

d) closing the container.

41. (previously presented) The process of claim 40, wherein the solid composition is prepared in an atmosphere having an oxygen content of less than about 0.01 moles per liter.

42. (previously presented) A process for increasing the stability of a composition in a closed container comprising:

a) preparing a solid composition comprising a meiosis activation substance having an oxygen content of less than about 0.01 moles per liter and an additive;

b) filling the solid composition into the container;

c) filling the container with an atmosphere having an oxygen content of less than 10%; and

d) closing the container.

43. (new) A method for preparing a solution comprising a meiosis activating substance comprising:

a) providing a container containing a pharmaceutical composition comprising a solid meiosis activating substance and an additive; and

b) contacting the pharmaceutical composition with an aqueous medium so as to form an aqueous solution comprising a dissolved form of the solid meiosis activating substance.

44. (new) The method of claim 43, wherein the pharmaceutical composition is maintained in the container in a closed state in an atmosphere with an oxygen content of less than 10% prior to contact with aqueous medium.

45. (new) The method of claim 44, wherein (a) the aqueous medium has an organic solvent content of less than about 0.1%; (b) the meiosis activating substance in the aqueous solution is in a concentration of at least about 100 μg/ml; or (c) the aqueous medium has an organic solvent content of less than about 0.1% and the meiosis activating substance in the aqueous solution is in a concentration of at least about 100 μg/ml.

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REMARKS

As a general matter, Applicants wish to thank Examiner Foster for the conscientious review of the applications and for providing helpful suggestions for moving this case towards allowance.

Period for Response

As reported to Examiner Foster by the undersigned on July 28, 2004, the Office Action mailed February 18, 2004 was never received by Applicants. PAIR records indicate that the Office Action was apparently returned to the Office on March 3, 2003 and apparently no further action was taken by the Office concerning it.

A formal customer number request was previously made in connection with this patent application prior to the mailing of the February 18, 2004 Office Action and, in accordance with the Office's instructions to Applicants' representative, Applicants' representative's customer number and request to use the same was also included in the most recently filed Amendment (Novo Nordisk® Pharmaceuticals has been instructed by the USPTO to make such an indication in all of our papers due to the *repeated* failure of the USPTO to use our correct address with any consistency). The fact that the Office Action was mailed and never received was only recently discovered during a regular (unspecific) review of applications associated with representative's customer number in Private PAIR on about July 22, 2004. Novo Nordisk Pharmaceuticals has had numerous cases mishandled in this matter and in all such cases to date the USPTO has reset the period for response.

In this respect, and at Examiner Foster's request, a Petition to the TC Director under 37 CFR 1.181 and in accordance with MPEP § 710.06 and 1160 OG 14, requesting resetting of the period for response to the February 18, 2004 Office Action, is submitted concurrently herewith (a copy is enclosed herewith).

Claim Amendments

Claims 5-6, 8-20, and 23-36 are amended to clarify the claim elements and thereby obviate the issues raised in the Office Action. The majority of these amendments are to the form of the claim, rather than the substance, and they do not narrow the scope of these claim elements or

represent any sort of surrender of the scope of the claimed subject matter. New independent claim 43 and new claims 44-45, which depend thereon, are directed to preparing an aqueous solution comprising a meiosis activating substance and claims 31-36, which appear to be more amenable to methods, are amended to be dependent on new claim 43. Claim 30 is amended so as to present an independent claim, which is free of some of the elements of claim 5. These claims and amendments find support in, e.g., the original claims and Examples 3, 4, and 6. The other claim amendments also are fully supported by the specification and original claims. No new matter is added. Claims 1, 3-6, and 8-45 are pending.

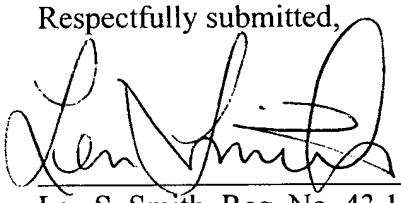
The Office Action

The Office Action rejected claims 5-20 and 23-26 under 35 U.S.C. § 112, first paragraph, as allegedly encompassing subject matter that is not adequately supported by the description and under 35 U.S.C. § 112, second paragraph, for being allegedly indefinite. Both rejections relate to the way that the term "atmosphere" is applied in claim 5 and the use of the term "composition" to describe various claim elements in claim 5 and claims dependent thereon. Specific rejections were raised under Section 112 concerning particular language in claims 26 and 29 that are obviated by the amendments to these claims, which removes the phrases that were the basis of these rejections. These also are clarifying amendments and do not serve to narrow the scope of these claims.

As indicated above, for clarity's sake, claim 5 has been amended such that it is directed to a "product" that comprises a container and a "pharmaceutical composition" contained in a low oxygen atmosphere in the container. The implication of the relationship between the atmosphere and the container is clear (i.e., the container contains the pharmaceutical composition in a low oxygen content atmosphere as specified in the claims). The pharmaceutical composition comprises a "meiosis activating substance" and an additive. Thus, claim 5 only uses the term "composition" to refer to a single claim element (the "pharmaceutical composition"), obviating any confusion that may have arisen from the previously proposed claim language. Claim 31, which has been made independent by this amendment, uses a similar set of claim elements. It is believed that the new claim language addresses the issues raised in the Office Action under Section 112.

In view of the claim amendments and remarks made herein, it is respectfully submitted that all of the pending claims are in condition for allowance. Early action to that end is respectfully requested. The Commissioner is hereby authorized to charge any fees in connection with this application and to credit any overpayments to Deposit Account No. 14-1447. The Examiner is invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,



Date: August 4, 2004

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Use the following customer number for all correspondence regarding this application.

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